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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,318	10/24/2003	John S. Patton	0001.13	8226

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,318	PATTON ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2,4,6-11,13,15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen ('084) in view of Saifer et al. ('224).

As to claim 2, Hansen discloses an apparatus for producing aerosolized medicament, the apparatus comprising: a reservoir (27,28) containing powder medicament to be aerosolized; and a chamber (46) comprising an inlet (47) and a mouthpiece (49), wherein gas (43) may flow into the chamber through the inlet and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament, wherein at least 40% by weight of the powder medicament is suspended by the gas (col.1, lines 38-44) in the chamber for delivery through the mouthpiece.

The difference between Hansen and claim 2 is the powder medicament comprising a protein or polypeptide.

Saifer et al. teach a protein (e.g. orgotein) in the form of a powder medicament for administration to a patient suffering from smoke inhalation.

It would have been obvious to modify the powdered medicament of Hansen to administer a variety of powdered medicaments using the Hansen device including

orgotein because it would have provided a means for treating patients suffering from smoke inhalation as taught by Saifer et al..

As to claims 4,13, Hansen discloses a source of compressed gas (43), wherein the compressed gas may be released from the source of compressed gas to cause the flow of gas to aerosolized the medicament (27,28).

As to claims 6,15, the chamber (46) of Hansen is cylindrical.

As to claims 7,16, Hansen discloses the generation of particles of a size that will enable deeper penetration into the respiratory tract of a patient (col.5, lines 37-50).

As to claims 8,17, Hansen discloses particle size range to predominate (90%) below 5 microns.

As to claims 9,10,18,19, Hansen as discussed above with respect to claim 2, discloses at least 55% and at least 70% by weight of the powdered medicament being suspended by the gas in the chamber for delivery through the mouthpiece (col.1, lines 38-44).

Claim 11 is substantially equivalent in scope to claim 2 and is included in Hansen as modified by Saifer et al. for the reasons set forth above with respect to claim 2.

3. Claims 3,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen ('084) in view of Saifer et al. ('224) as applied to claims 2,4,6-11,13,15-19 above, and further in view of Moren et al. ('712).

As to claim 3, while Hansen is silent as to the dimensions of the chamber, the chamber size can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular chamber size including 100ml to

750ml. The treatment of adult patients vs. children would require a larger chamber due to increased tidal volume and lung capacity of adults. Otherwise, resort is had to Moren which teaches an expansion chamber having a volume in the range of 500ml to 2000ml (see figure) for reducing propellent and generating smaller medicament particles which will more readily follow the path of inhalation (see abstract). It would have been obvious to further modify the chamber of Hansen because it would have provided a means for reducing propellent and generating smaller medicament particles which will more readily follow the path of inhalation as taught by Moren.

Claim 12 is substantially equivalent in scope to claim 3 and is included in Hansen as further modified by Moren et al. for the reasons set forth above with respect to claim 3.

4. Claims 5,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen ('084) in view of Saifer et al. ('224) as applied to claims 2,4,6-11,13,15-19 above, and further in view of Nowacki et al. ('343).

The difference between Hansen as modified by Saifer et al. and claim 5 is the chamber being adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation.

Nowacki et al., in an apparatus for producing aerosolized medicament, teach a chamber being adapted to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation for the purpose of insuring substantially complete inhalation of medicament and for providing improved dispersion of medicament to form very small droplets and mist within the chamber (col.1, lines 54-56 and col.2, lines 12-14).

It would have been obvious to further modify the chamber of Hansen to adapt it to contain the aerosolized medicament for subsequent delivery to a patient during a patient's inhalation because it would have insured substantially complete inhalation of medicament and provided improved dispersion of medicament to form very small droplets and mist within the chamber as taught by Nowacki et al..

Claim 14 is substantially equivalent in scope to claim 5 and is included in Hansen as further modified by Nowacki et al. for the reasons set forth above with respect to claim 5.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant devices for producing aerosolized medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 18, 2005